

## Author Index for Volume 24

- Abdalla, M, 736  
ADAPT investigators, 462  
Anbar, D, 51  
Anderson, J, 702  
Anderson, K, 39  
Angiotensin-Converting Enzyme Inhibition in Progressive Renal Disease (AIPRD) Study Group, 324  
Apfel, CC, 736  
AVID Investigators, 341
- Babiker, A, 481, 643  
Bain, RP, 224  
Baker, RS, 294  
Bangdiwala, SI, 78  
Barnett, M, 39  
Bautista, OM, 224  
Beanlands, R, 776  
Benard, F, 776  
BENEDICT Group, 442  
Berger, VW, 156  
Berman, N, 422  
Bernardo, J, 245  
Bhandari, M, 719  
Biedler, A, 736  
Black, S, 643  
Bock, N, 245  
Boe, K, 422  
Bots, ML, 752  
Bowen, DJ, 39  
Braun, TM, 669  
Brawer, MK, 224  
Breese, P, 245  
Breitfeld, PP, 702  
Broderick, JE, 182  
Brown, MB, 629  
Brown, ST, 481  
Brubaker, L, 629  
Buchanan, SL, 289S  
Buckelew, JM, 570  
Burman, W, 245
- Califf, RM, 256  
Cameron, W, 481
- Carroll, KJ, 682  
CAST Investigators, 341  
Chacon, FR, 289S  
Chappell, R, 135, 506  
Charleston, S, 643  
Chen, YHJ, 16  
Chen-Mok, M, 78  
Cheung, Y-B, 110  
Children's Amalgam Trial Study Group, 795  
Chlebowski, RT, 422  
Chung, Y-FA, 110  
Clark, M, 591  
Clayton, D, 66  
Clipp, EC, 206  
Coates, G, 776  
Cohen, HJ, 206  
Collins, JF, 71, 726, 269S, 277S, 298S, 306S, 316S  
Connelly, LB, 544  
Copas, A, 643  
Crawford, ED, 224  
Crist, WM, 702  
CTNS Study Group, 815  
Cundiff, G, 629
- DeGruttola, V, 122  
de Haan, RJ, 390  
deKemp, RA, 776  
Delgado-Herrera, L, 51  
DeMets, DL, 16, 256  
Denes, P, 341  
Demark-Wahnefried, W, 206  
De Serres, G, 99  
Dickersin, K, 294, 591  
Digitalis Investigation Group (DIG) Investigators, 726, 269S, 277S, 289S, 298S, 306S, 316S  
DiRienzo, AG, 122  
Dominik, R, 78  
Donovan, JL, 272  
Duval, B, 99
- Egan, D, 269S, 277S, 298S, 316S
- Ellenberg, SS, 201, 585  
Ettinger, WH, 462  
Evans, GW, 752
- Fallen, E, 776  
Feldon, SE, 294  
Ferrara, JLM, 669  
Feussner, JR, 570  
Fine, JP, 135  
Fine, P, 629  
Forrest, S, 643  
Frick, KD, 591  
Friedman, L, 341  
Fye, CL, 289S
- Gagne, WH, 289S  
Ganju, J, 167, 830  
Garg, R, 269S, 277S, 289S, 298S, 306S, 316S  
Gazzard, B, 481  
Geller, N, 269S, 316S  
Giatras, I, 324  
Gilpin, AMK, 92  
Glas, CAW, 390  
Gönen, M, 355  
Goodman, G, 39  
Goodman, SN, 256  
Grambsch, PM, 105  
Granadier, RJ, 294  
Granek, I, 422  
Grobbee, DE, 752
- Haakenson, CM, 570  
Hallstrom, A, 341  
Hamdy, FC, 272  
Hashimoto, S, 560  
Hays, M, 78  
Heller, G, 353  
Helmond, FA, 752  
Hendry, P, 776  
Hillman, DW, 85  
Hinotsu, S, 560  
Holbrook, JT, 92  
Holman, R, 390  
Holodniy, M, 481  
Hooper, FJ, 294  
Horney, A, 277S  
Horney, RA, 726

- Howell, CL, 726, 277S, 306S  
 Huber, M, 422  
 Hufford, MR, 182  
 Humen, D, 776  
 Hung, HMJ, 147  
 Hunsberger, S, 4  
 Huo, D, 506  
  
 Iafrate, RP, 256  
 Irsula, B, 78  
 Ischemic Optic Neuropathy Decompression Trial Research Group, 294  
 Iwanochko, RM, 776  
  
 Jabs, DA, 92  
 Jackson, M, 422  
 Jacoby, A, 272  
 Jafar, TH, 324  
 Jarjoura, D, 306  
 Ji, M, 283  
 Jiang, H, 135  
 Johns, A, 591  
 Johnson, AM, 643  
 Jones, LA, 711  
 Jones, MS, 289S  
 Juritz, J, 440  
  
 Kaplan, SA, 224  
 Karim, T, 324  
 Karrison, TG, 506  
 Kawado, M, 560  
 Kelman, S, 294  
 Kent, E, 298S  
 Kirk, G, 277S  
 Korttila, K, 736  
 Kosmorsky, GS, 294  
 Kranke, P, 736  
 Kusek, JW, 224  
 Kyriakides, TC, 481  
  
 Lan, KKG, 16  
 Landa, M, 324  
 Langenberg, P, 591  
 Leece, P, 719  
 Lepor, H, 224  
 Levey, AS, 324  
 Levine, JE, 669  
 Liu, Q, 4  
 Liuni, C, 298S  
 Loeser, RF, 462  
 Look AHEAD Research Group, 610  
 Louis, TA, 85  
  
 Machin, D, 110  
 Magder, LS, 411  
  
 Makarewicz, VA, 156  
 Martin, S, 298S  
 Mathew, J, 316S  
 Matsuyama, Y, 560  
 Matthews, JNS, 200  
 McBride, KH, 752  
 McCarney, R, 731  
 McConnell, JD, 224  
 McSherry, F, 277S  
 Mehrotra, DV, 167, 830  
 Meijer, R, 752  
 Meinert, CL, 92  
 Messier, SP, 462  
 Migrino, RQ, 501  
 Milas, C, 422  
 Miller, G, 224  
 Miller, GD, 462  
 Mills, N, 272  
 Morey, MC, 206  
 Morgan, CC, 523  
 Morgan, T, 462  
 Morris, M, 341  
 Morse, MA, 256  
 MTOPS Research Group, 224  
 Munro, M, 591  
 Mutti, DO, 711  
  
 Neal, DE, 272  
 Neaton, JD, 1, 2, 109, 667  
 Nelson, DK, 256  
 Nichol, G, 776  
 Nyberg, LM, Jr, 224  
 Nygaard, I, 629  
  
 Oakley, A, 643  
 Oden, NL, 28  
 Ohashi, Y, 560  
 Omenn, G, 39  
 OPAL Investigators, 752  
 OPTIMA Study Team, 481  
  
 PARR-2 Investigators, 776  
 Paskett, ED, 752  
 Peipert, JF, 591  
 Pelvic Floor Disorders Network, 629  
 Petruckevitch, A, 643  
 Phelps, DL, 28  
 Philbin, E, 316S  
 Pieper, CF, 206  
 Pocock, SJ, 736  
 Powell, C, 39  
 Proschan, MA, 4  
  
 Qu, RP, 436  
  
 Racine, N, 776  
 Raisch, DW, 570, 289S  
  
 Reddy, M, 324  
 Rejeski, WJ, 462  
 Rezvani, A, 156  
 Richter, H, 629  
 Riley, W, 752  
 Rizo-Patron, C, 341  
 Roewer, N, 736  
 Ross, H, 776  
 Ruddy, TD, 776  
  
 Sarr, M, 589  
 Sather, MR, 570, 289S  
 Schechter, MT, 481  
 Scheifele, D, 99  
 Schemitsch, E, 719  
 Scherer, R, 294, 591  
 Schmid, CH, 324  
 Schwartz, JE, 182  
 Seiff, SR, 294  
 Sevvick, MA, 462  
 Shiffman, S, 182  
 Sihelnik, SA, 224  
 Singer, J, 481  
 Skowronski, DM, 99  
 Sloane, R, 206  
 Smith, M, 272  
 Snetselaar, L, 422  
 Snyder, DC, 206  
 Sokal, DC, 78  
 Song, JX, 378  
 Spence, E, 277S  
 Spivak, J, 422  
 Sprague, S, 719  
 S.P.R.I.N.T. Investigators, 719  
 Stark, PC, 324  
 Stephenson, JM, 643  
 Stinnett, S, 277S  
 Stone, AA, 182  
 STOP-DUB Research Group, 591  
 STOP-ROP Multicenter Study Group, 28  
 Strange, V, 643  
 Studies of Ocular Complications of AIDS Research Group, 92  
 Sugarman, J, 256  
 Swiontkowski, MF, 719  
  
 Tai, B-C, 110  
 Tan, S-B, 110  
 Tang, M-L, 364  
 Teo, KK, 306S  
 Thornquist, M, 39  
 Topol, EJ, 501  
 Tornetta, P, III, 719  
 Tuberculosis Trials Consortium, 245

Ullrich, F, 702

Vernon, A, 245

Vickers, AJ, 731

Visco, A, 629

Walline, JJ, 711

Wang, S-J, 147

Wassell, JT, 378

Weber, A, 591, 629

Weir, AB, 201

Weis, S, 245

Wells, G, 776

Wheatley, K, 66

Williamson, JD, 462

Williford, WO, 269S,  
277S, 289S, 306S

Wittes, J, 256

Xiong, C, 283

Yamaguchi, T, 560

Yan, Y, 283

Youle, M, 481

Yusuf, S, 269S, 277S,  
289S, 316S

Zadnik, K, 711

Zheng, H, 436

Zyczynski, H, 629

## Subject Index for Volume 24

### ABSTRACTS

Third joint meeting of the Society for Clinical Trials and the International Society for Clinical Biostatistics, 43S

### ADAPTIVE DESIGN

Practical midcourse sample size modification in clinical trials, 4

### ADHERENCE/COMPLIANCE

Patient compliance with paper and electronic diaries, 182

Research staff turnover and participant adherence in the Women's Health Initiative, 422

### AIDS/HIV

An open-label randomized clinical trial of novel therapeutic strategies for HIV-infected patients in whom antiretroviral therapy has failed: rationale and design of the OPTIMA Trial, 481

Data and safety monitoring board deliberations resulting in the early termination of the Monoclonal Antibody Cytomegalovirus Retinitis Trial, 92

Design and analysis of clinical trials with a bivariate failure time endpoint, with application to AIDS Clinical Trials Group Study A5142, 122

DSMB case study: decision making when a similar clinical trial is stopped early, 85

Estimating the distribution of nonterminal event time in the presence of mortality or informative dropout, 135

### ANESTHETICS AND ANTIEMETICS

An International Multicenter Protocol to Assess the single and combined benefits of antiemetic interventions in a Controlled clinical Trial of a  $2 \times 2 \times 2 \times 2 \times 2 \times 2$  factorial design (IMPACT), 736

### ARRHYTHMIA

Do arrhythmia patients improve survival by participating in randomized clinical trials? Observations from the Cardiac Arrhythmia Suppression Trial (CAST) and the Antiarrhythmics Versus Implantable Defibrillators Trial (AVID), 341

### AUTOIMMUNE DISEASE

A model for the interim analysis process: a case study, 51

### BIAS

Estimation following group-sequential response-adaptive clinical trials, 523

### BOOK REVIEWS

*Analysis of Failure and Survival Data*, 353

*Data Monitoring Committees in Clinical Trials: A Practical Perspective*, 105

*Drug Safety Evaluation*, 201

*A Manager's Guide to the Design and Conduct of Clinical Trials*, 589

*Randomization in Clinical Trials: Theory and Practice*, 200

*Statistical Methods in Medical Research* fourth edition, 440

### CANCER

Be skeptical about unexpected large apparent treatment effects: the case of an MRC AML12 randomization, 66

Elicitation of prior distributions for a phase III randomized controlled trial of adjuvant therapy with surgery for hepatocellular carcinoma, 110

Leading the Way in Exercise and Diet (Project LEAD): intervening to improve function among older breast and prostate cancer survivors, 206

Planning for subgroup analysis: a case study of treatment-marker interaction in metastatic colorectal cancer, 355



Stopping the active intervention: CARET, 39

Web-based decision support for clinical trial eligibility determination in an international clinical trials network, 702

#### **CARDIOVASCULAR DISEASE**

Evaluation of outcome and cost-effectiveness using an FDG PET-guided approach to management of patients with coronary disease and severe left ventricular dysfunction (PARR-2): rationale, design, and methods, 776

Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes, 610

The Osteoporosis Prevention and Arterial effects of tiboLone (OPAL) study: design and baseline characteristics, 752

#### **CHILDREN**

The Children's Amalgam Trial: design and methods, 795

A school-based randomized controlled trial of peer-led sex education in England, 643

Statistical issues related to early closure of STOP-ROP, a group-sequential trial, 28

Use of a run-in period to decrease loss to follow-up in the Contact Lens and Myopia Progression (CLAMP) study, 711

Web-based decision support for clinical trial eligibility determination in an international clinical trials network, 702

#### **CLOSEOUT ACTIVITIES**

Determination of vital status at the end of the DIG trial, 726

Stopping the active intervention: CARET, 39

#### **CLUSTER SAMPLES**

Balancing the number and size of sites: an economic approach to the optimal design of cluster samples, 544

#### **COCHRAN'S STATISTIC**

Sample size for  $K \times 2$  tables in equivalence studies using Cochran's statistic, 378

#### **CONSENT**

The effects of local review on informed consent documents from a multicenter clinical trials consortium, 245

#### **CONTACT LENS**

Use of a run-in period to decrease loss to follow-up in the Contact Lens and Myopia Progression (CLAMP) study, 711

#### **CONTROLS**

Crossing controls to treatment in repeated-measures trials, 306

#### **COORDINATING CENTER**

The role of the data coordinating center in the DIG trial, 277S

The role of the data coordinating center in the IRB review and approval process: the DIG trial experience, 306S

The role of the pharmacy coordinating center in the DIG trial, 289S

The use of regional coordinating centers in large clinical trials: the DIG trial, 298S

#### **CROSSOVER DESIGNS**

Sample size calculation for bioequivalence studies with high-order crossover designs, 436

#### **CYTOMEGALOVIRUS**

Data and safety monitoring board deliberations resulting in the early termination of the Monoclonal Antibody Cytomegalovirus Retinitis Trial, 92

DSMB case study: decision making when a similar clinical trial is stopped early, 85

#### **DATA AND SAFETY MONITORING BOARD (DSMB)**

Be skeptical about unexpected large apparent treatment effects: the case

- of an MRC AML12 randomization, 66
- Data and safety monitoring board deliberations resulting in the early termination of the Monoclonal Antibody Cytomegalovirus Retinitis Trial, 92
- Data and safety monitoring board issues raised in the VA Status Epilepticus Study, 71
- DSMB case study: decision making when a similar clinical trial is stopped early, 85
- A matter of life and death? The Heart Protection Study and protection of clinical trial participants, 501
- A model for the interim analysis process: a case study, 51
- Monitoring mortality at interim analyses while testing a composite endpoint at the final analysis, 16
- Promoting good clinical practices in the conduct of clinical trials: experiences in the Department of Veterans Affairs Cooperative Studies Program, 570
- Statistical issues related to early closure of STOP-ROP, a group-sequential trial, 28
- Stopping the active intervention: CARET, 39
- Termination of a randomized controlled trial of two vasectomy techniques, 78
- Toward protecting the safety of participants in clinical trials, 256
- Unique roles of a data and safety monitoring board in vaccine safety trials with compressed timelines and urgent implications, 99

#### DATA VERIFICATION

- A comparison of error detection rates between the reading aloud method and the double data entry method, 560

#### DECISION SUPPORT TOOL

- Web-based decision support for clinical trial eligibility determination in an international clinical trials network, 702

#### DENTAL RESTORATION

- The Children's Amalgam Trial: design and methods, 795

#### DESIGN PAPERS. *See also* LARGE SIMPLE TRIAL

- The Arthritis, Diet and Activity Promotion Trial (ADAPT): design, rationale, and baseline results, 462
- The BErgamo NEphrologic Diabetes Complications Trial (BENEDICT): design and baseline characteristics, 442
- The Children's Amalgam Trial: design and methods, 795
- Evaluation of outcome and cost-effectiveness using an FDG PET-guided approach to management of patients with coronary disease and severe left ventricular dysfunction (PARR-2): rationale, design, and methods, 776
- An International Multicenter Protocol to Assess the single and combined benefits of antiemetic interventions in a Controlled clinical Trial of a  $2 \times 2 \times 2 \times 2 \times 2 \times 2$  factorial design (IMPACT), 736
- The Italian-American Clinical Trial of Nutritional Supplements and Age-Related Cataract (CTNS): design implications. CTNS report no. 1, 815
- Leading the Way in Exercise and Diet (Project LEAD): intervening to improve function among older breast and prostate cancer survivors, 206
- Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes, 610
- An open-label randomized clinical trial of novel therapeutic strategies for HIV-infected patients in whom antiretroviral therapy has failed: rationale and design of the OPTIMA Trial, 481
- The Osteoporosis Prevention and Arterial effects of tiboLone (OPAL) study: design and baseline characteristics, 752
- A randomized trial of colpopexy and urinary reduction efforts (CARE): design and methods, 629
- A school-based randomized controlled trial of peer-led sex education in England, 643
- Study design of the Medical Therapy of Prostatic Symptoms (MTOPS) trial, 224
- Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleed-

ing (STOP-DUB): design and methods, 591

### DIABETES

The BErgamo NEphrologic Diabetes Complications Trial (BENEDICT): design and baseline characteristics, 442

Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes, 610

### DIARIES

Patient compliance with paper and electronic diaries, 182

### DOSE REASSIGNMENT

Determining a maximum tolerated cumulative dose: dose reassignment within the TITE-CRM, 669

### ENDPOINT

Design and analysis of clinical trials with a bivariate failure time endpoint, with application to AIDS Clinical Trials Group Study A5142, 122

Estimating the distribution of nonterminal event time in the presence of mortality or informative dropout, 135

Monitoring mortality at interim analyses while testing a composite endpoint at the final analysis, 16

### ETHICS

Are all monitoring boundaries equally ethical? 585

A matter of life and death? The Heart Protection Study and protection of clinical trial participants, 501

Promoting good clinical practices in the conduct of clinical trials: experiences in the Department of Veterans Affairs Cooperative Studies Program, 570

Toward protecting the safety of participants in clinical trials, 256

### FOLLOW-UP

Determination of vital status at the end of the DIG trial, 726

Limiting loss to follow-up in a multicenter randomized trial in orthopedic surgery, 719

Use of a run-in period to decrease loss to follow-up in the Contact Lens and Myopia Progression (CLAMP) study, 711

Use of a single global assessment to reduce missing data in a clinical trial with follow-up at one year, 731

### GOOD CLINICAL PRACTICE

Promoting good clinical practices in the conduct of clinical trials: experiences in the Department of Veterans Affairs Cooperative Studies Program, 570

### INSTITUTIONAL REVIEW BOARD

The effects of local review on informed consent documents from a multicenter clinical trials consortium, 245

The role of the data coordinating center in the IRB review and approval process: the DIG trial experience, 306S

Toward protecting the safety of participants in clinical trials, 256

### INTERIM ANALYSIS

Are all monitoring boundaries equally ethical? 585

Estimation following group-sequential response-adaptive clinical trials, 523

A group sequential, response-adaptive design for randomized clinical trials, 506

A model for the interim analysis process: a case study, 51

Termination of a randomized controlled trial of two vasectomy techniques, 78

### ITEM RESPONSE THEORY

Power analysis in randomized clinical trials based on item response theory, 390

### LARGE SIMPLE TRIAL

Determination of vital status at the end of the DIG trial, 726



- Key personnel of DIG trial, 327S
- Lessons learned from the DIG trial, 316S
- Overview of the DIG trial, 269S
- The role of the data coordinating center in the DIG trial, 277S
- The role of the data coordinating center in the IRB review and approval process: the DIG trial experience, 306S
- The role of the pharmacy coordinating center in the DIG trial, 289S
- The use of regional coordinating centers in large clinical trials: the DIG trial, 298S

#### **LIFESTYLE INTERVENTION**

- The Arthritis, Diet and Activity Promotion Trial (ADAPT): design, rationale, and baseline results, 462
- Leading the Way in Exercise and Diet (Project LEAD): intervening to improve function among older breast and prostate cancer survivors, 206
- Look AHEAD (Action for Health in Diabetes): design and methods for a clinical trial of weight loss for the prevention of cardiovascular disease in type 2 diabetes, 610
- Sample sizes for comparing means of two lifetime distributions with type II censored data: application in an aging intervention study, 283
- A school-based randomized controlled trial of peer-led sex education in England, 643

#### **META-ANALYSIS**

- Constructing a database of individual clinical trials for longitudinal analysis, 324

#### **MISSING DATA**

- Simple approaches to assess the possible impact of missing outcome information on estimates of risk ratios, odds ratios, and risk differences, 411
- Use of a single global assessment to reduce missing data in a clinical trial with follow-up at one year, 731

#### **MORTALITY**

- Data and safety monitoring board issues raised in the VA Status Epilepticus Study, 71

- Do arrhythmia patients improve survival by participating in randomized clinical trials? Observations from the Cardiac Arrhythmia Suppression Trial (CAST) and the Antiarrhythmics Versus Implantable Defibrillators Trial (AVID), 341

- Estimating the distribution of nonterminal event time in the presence of mortality or informative dropout, 135

- A matter of life and death? The Heart Protection Study and protection of clinical trial participants, 501

- Monitoring mortality at interim analyses while testing a composite endpoint at the final analysis, 16

#### **MULTICENTER TRIALS**

- The effects of local review on informed consent documents from a multicenter clinical trials consortium, 245
- Stratified experiments reexamined with emphasis on multicenter trials, 167; correction, 830

#### **NONINFERIORITY**

- Assessing treatment efficacy in noninferiority trials, 147
- Matched-pair noninferiority trials using rate ratio: a comparison of current methods and sample size refinement, 364

#### **PAIN, CHRONIC**

- Patient compliance with paper and electronic diaries, 182

#### **PRIOR ELICITATION**

- Elicitation of prior distributions for a phase III randomized controlled trial of adjuvant therapy with surgery for hepatocellular carcinoma, 110

#### **QUALITY ASSURANCE**

- Surgical quality assurance in the Ischemic Optic Neuropathy Decompression Trial (IONDT), 294

#### **RECRUITMENT**

- Data and safety monitoring board issues raised in the VA Status Epilepticus Study, 71



- Direct effect on validity of response run-in selection in clinical trials, 156
- Perceptions of equipoise are crucial to trial participation: a qualitative study of men in the ProtecT study, 272
- Statistical issues related to early closure of STOP-ROP, a group-sequential trial, 28
- Web-based decision support for clinical trial eligibility determination in an international clinical trials network, 702

#### REGRESSION

- Planning for subgroup analysis: a case study of treatment-marker interaction in metastatic colorectal cancer, 355

#### RENAL DISEASE

- Constructing a database of individual clinical trials for longitudinal analysis, 324

#### REPEATED-MEASURES TRIAL

- Crossing controls to treatment in repeated-measures trials, 306

#### RESPONSE-ADAPTIVE DESIGN

- Estimation following group-sequential response-adaptive clinical trials, 523
- A group sequential, response-adaptive design for randomized clinical trials, 506

#### RUN-IN

- Direct effect on validity of response run-in selection in clinical trials, 156
- Use of a run-in period to decrease loss to follow-up in the Contact Lens and Myopia Progression (CLAMP) study, 711

#### SAMPLE SIZE

- Balancing the number and size of sites: an economic approach to the optimal design of cluster samples, 544
- A group sequential, response-adaptive design for randomized clinical trials, 506
- Matched-pair noninferiority trials using rate ratio: a comparison of current methods and sample size refinement, 364

- Planning for subgroup analysis: a case study of treatment-marker interaction in metastatic colorectal cancer, 355

- Power analysis in randomized clinical trials based on item response theory, 390

- Practical midcourse sample size modification in clinical trials, 4

- Sample size calculation for bioequivalence studies with high-order crossover designs, 436

- Sample size for  $K \times 2$  tables in equivalence studies using Cochran's statistic, 378

- Sample sizes for comparing means of two lifetime distributions with type II censored data: application in an aging intervention study, 283

- Stratified experiments reexamined with emphasis on multicenter trials, 167; correction, 830

#### SIMULATION STUDY

- Design and analysis of clinical trials with a bivariate failure time endpoint, with application to AIDS Clinical Trials Group Study A5142, 122

- Determining a maximum tolerated cumulative dose: dose reassignment within the TITE-CRM, 669

- Estimating the distribution of nonterminal event time in the presence of mortality or informative dropout, 135

- Estimation following group-sequential response-adaptive clinical trials, 523

- A group sequential, response-adaptive design for randomized clinical trials, 506

- Planning for subgroup analysis: a case study of treatment-marker interaction in metastatic colorectal cancer, 355

#### STAFF TURNOVER

- Research staff turnover and participant adherence in the Women's Health Initiative, 422

#### STOPPING RULES

- Are all monitoring boundaries equally ethical? 585
- Be skeptical about unexpected large apparent treatment effects: the case of an MRC AML12 randomization, 66

- Statistical issues related to early closure of STOP-ROP, a group-sequential trial, 28
- Stopping the active intervention: CARET, 39
- Termination of a randomized controlled trial of two vasectomy techniques, 78

## **SURGERY**

- Elicitation of prior distributions for a phase III randomized controlled trial of adjuvant therapy with surgery for hepatocellular carcinoma, 110
- An International Multicenter Protocol to Assess the single and combined benefits of antiemetic interventions in a Controlled clinical Trial of a  $2 \times 2 \times 2 \times 2 \times 2 \times 2$  factorial design (IMPACT), 736
- Limiting loss to follow-up in a multicenter randomized trial in orthopedic surgery, 719
- A matter of life and death? The Heart Protection Study and protection of clinical trial participants, 501
- A randomized trial of colpopexy and urinary reduction efforts (CARE): design and methods, 629
- Surgical quality assurance in the Ischemic Optic Neuropathy Decompression Trial (IONDT), 294
- Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB): design and methods, 591

## **TWO-STAGE DESIGN**

- Practical midcourse sample size modification in clinical trials, 4

## **WEIBULL MODEL**

- On the use and utility of the Weibull model in the analysis of survival data, 682
- Sample sizes for comparing means of two lifetime distributions with type II censored data: application in an aging intervention study, 283

## **WOMEN'S HEALTH**

- Leading the Way in Exercise and Diet (Project LEAD): intervening to improve function among older breast and prostate cancer survivors, 206
- The Osteoporosis Prevention and Arterial effects of tiboLone (OPAL) study: design and baseline characteristics, 752
- A randomized trial of colpopexy and urinary reduction efforts (CARE): design and methods, 629
- Research staff turnover and participant adherence in the Women's Health Initiative, 422
- Surgical Treatments Outcomes Project for Dysfunctional Uterine Bleeding (STOP-DUB): design and methods, 591